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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,119	04/12/2004	Walter Muller	512100-2034	3517

20999 7590 07/09/2008
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,119	MULLER, WALTER	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 03/31/2008.

Claims 1-20 are pending and included in the prosecution.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-13,16,17,23-26 and 28-31 of copending Application No. 10/835,997 in view of US 6,348,501 ('501).

The subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are subject matter as follows: transdermal patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent.

However, the present claims are different from the copending claims because the copending claims not claiming capsaicin while the present claims recite capsaicin.

US '501 teaches capsaicin to treat pain administered topically in encapsulated form to reduce the inflammatory effect on capsaicin on the skin (abstract; col.3, lines 13-19; col.4, lines 56-60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent as claimed by the copending application '997, and deliver capsaicin disclosed by US '501 in the microreservoirs claimed by the copending application because US '501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, with reasonable expectation of having patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent to be delivered to the skin without causing any inflammation to the skin at the site of application of the patch.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

3. Applicant's arguments filed 03/31/2008 have been fully considered but they are not persuasive. Applicant argues that that the double-patenting rejection has been rendered moot because the scope of the active substances in the '997 application has been limited to estradiol hemihydrate, bupranolol and testosterone in the amendment which was filed on 15 February 2008 and the scope of the active substances in the present case has been limited to capsaicin and analogs thereof.

In response to this argument, it is argued that the present claims are obvious over the claims pending in copending application US '997 in view of US '501. The copending application claims transdermal delivery system having the same structure and composition as the instantly claimed. Therefore, at the time of the invention the structure of the claimed transdermal device was known. US '501 teaches capsaicin delivered transdermally in encapsulated form to reduce its inflammatory effect on the skin. Therefore, combination of the claims pending in US '997 and the teaching of US '501 would have resulted in the present claims, see section 2 of this office action.

Specification

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-11, 13-15, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,788,983 ('983) in view of US 6,348,501 ('501), US 6,818,671 ('671) and US 2005/0079206 ('206).

US '983 teaches a transdermal polymer dosage unit comprising backing layer, and adhesive polymer reservoir layer comprising pharmaceuticals in microreservoirs (abstract; col.7, lines 24-25). The microreservoirs are formed by dissolving/dispersing the pharmaceuticals in the reservoir medium, combining with polymer material, stirring to form the microreservoirs, spreading of the mix onto backing layer and drying at 60 ^{0}C (col.7, lines 26-29; col.9, lines 17-34; col.15, lines 45-50). Suitable solvent or reservoir medium is diols including butanediol (col.8, lines 36-43). The amount of diols in the solvent is at least 20% (col.8, lines 45-48). The adhesive polymer can be silicone adhesive (col.9, lines 23-45). The microreservoirs may contain hydroxypropyl cellulose to provide the desired increased viscosity of the reservoir medium in small amount of between 1-4% (col.9, lines 7-15). Pharmaceuticals suitable to be delivered by this transdermal dosage form include NSAID and vasodilator (col.11, lines 43-55). The

pharmaceuticals are present in an amount less than saturation, i.e. less than 100% as required by claim 1 (col.9, lies 1-6). The backing layer is polyester having thickness of 10-200 μm (col.5, lines 47-60).

Although US '983 teaches suitability of the disclosed transdermal system to deliver analgesics and vasodilator drugs, however, the reference does not explicitly teach capsaicin as an active agent dissolved in the microreservoirs.

Although US '983 teaches silicone adhesive suitable for matrix or reservoir having microreservoirs comprising amphiphilic solvent and drug, however, the reference does not explicitly teach mixture of medium tack polysiloxane and high tack polysiloxane.

US '501 teaches capsaicin to treat pain administered topically in encapsulated form to reduce the inflammatory effect on capsaicin on the skin (abstract; col.3, lines 13-19; col.4, lines 56-60). Capsaicin is known to treat neuropathic.

US '671 teaches topical composition to treat topical pain and inflammation including neuralgia comprising wherein the topical composition comprises capsaicin and solvent system comprising 1,3, butylene glycol, dipropylene glycol, and diethylene glycol monoethyl ether (DGME), with DGME is preferred solvent (col.2, lines 16-37, 58; col.3, lines 8-16; col.4, example 3).

US '206 teaches transdermal device comprising microreservoirs containing drug in a self adhesive matrix, wherein the matrix is silicone adhesive made of mixture of high tack polysiloxane (BIO-PSA 4301) and medium tack polysiloxane (BIO-PSA 4201)

that is advantageous in providing optimum balance between good adhesion and little cold flux (abstract; paragraphs: 0054-0058).

Therefore, the prior art at the time of the invention recognized encapsulation of therapeutic agent in microreservoirs within silicone reservoir/matrix containing butanediol as disclosed by US '983, and also recognized encapsulation of capsaicin in topical formulation as disclosed by US '501 to avoid skin inflammation. The art further recognized suitability of amphiphilic solvent, to dissolve capsaicin, i.e. butanediol, dipropylene glycol and DGME, with DGME is the preferred solvents for formulation containing capsaicin as disclosed by US '671, and mixture of medium tack and high tack polysiloxane was also known as advantageous for adhesive for transdermal devices at the time of the invention.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal therapeutic system comprising a polymer matrix comprising silicone adhesive and microreservoirs containing therapeutic active agent in butanediol solvent as disclosed by US '983, and deliver capsaicin disclosed by US '501 and US '671 in the microreservoirs containing amphiphilic solvent disclosed by US '983 because US '501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, and further because US '671 disclosed that capsaicin is soluble effectively in butanediol and other amphiphilic solvents including DGME, with reasonable expectation of having transdermal device comprising silicone adhesive matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent to be delivered to the skin effectively to treat neuralgia without

causing any inflammation to the skin at the site of application of the device. Additionally, it would have been obvious tone having ordinary skill in the art at the time of the invention to deliver transdermal device comprising silicone adhesive matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '983, US '501 and US '671, and replace the silicone adhesive with mixture of high tack polysiloxane and medium tack polysiloxane as taught by US '206 because US '206 teaches that such a mixture is advantageous in providing optimum balance between good adhesion and little cold flux, with reasonable expectation of having transdermal device comprising microreservoirs comprising capsaicin and amphiphilic solvent and the microreservoirs are dispersed in matrix made of mixture of high tack polysiloxane and medium tack polysiloxane wherein the matrix has optimum balance between good adhesion and little cold flux.

The references do not teach the coating weight of the drug containing adhesive on the backing layer as claimed by claims 13 and 14. However, such coating weight would have been determined by one having ordinary skill in the art without undue experimentation based on the specific individual use. Therefore, such coating weight does not impart patentability of the claims in absence of superior and unexpected results obtained from this coating weight.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '983, US '501, US '671, and US '206 and further in view of US 7,247,315 ('315).

The combined teachings of US '983, US '501, US '671, and US '206 are previously discussed as set forth in section 6 of this office action.

Although the combined teachings of US '983, US '501, US '671, and US '206 teach mixture of polysiloxane adhesive polymers, however, does not teach silicone oil in the adhesive composition.

US '315 teaches transdermal delivery patch comprising drug matrix layer comprising polydimethylsiloxane and dimethicone (silicone oil) in an amount of 4-7% that acts as plasticizer for the polydimethylsiloxane and such an amount has as drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin (abstract; col.3, lines 21-25, 32-33, 39-45).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '983, US '501, US '671, and US '206, and further add 4-7% silicone oil to the polysiloxane matrix as disclosed by US '315 because US '315 teaches that 4-7% dimethicone when added to polysiloxane acts as plasticizer for the polysiloxane and has drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin, with reasonable expectation of having transdermal device comprising polysiloxane matrix containing microreservoirs comprising a capsaicin in an amphiphilic solvent and further comprising 4-7% silicone oil wherein the flux rate of capsaicin delivery through the skin is predictable and uniform.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '983, US '501, US '671, and US '206, and further in view of US 5,494,680 ('680).

The combined teachings of US '983, US '501, US '671, and US '206 are previously discussed as set forth in section 6 of this office action.

Although the combined teachings of US '983, US '501, US '671, and US '206 teach backing material, however, does not teach the specific backing materials as claimed by claim 16.

US '680 teaches transdermal delivery device having backing that is flexible such that the device conforms to the skin. The material of the backing can be polyester or ethylene vinyl acetate copolymer (col.4, line 60 till col.5, line 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polyester backing layer and polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '983, US '501, US '671, and US '206, and replace the polyester backing material with ethylene vinyl acetate copolymer as disclosed by US '680, because US '680 teaches backing made of such material is flexible such that the device conforms to the skin, with reasonable expectation of having transdermal device comprising backing layer of ethylene vinyl acetate copolymer and matrix of polysiloxane containing microreservoirs comprising a capsaicin in an amphiphilic solvent wherein the device is flexible and conforms to the skin, therefore comfortable to the user.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '983, US '501, US '671, and US '206, and further in view of US 6,239,680 ('180).

The combined teachings of US '983, US '501, US '671, and US '206 are previously discussed as set forth in section 6 of this office action.

Although the combined teachings US '983, US '501, US '671, and US '206 teach analgesic effect of capsaicin, and further teaches treating neuralgia, however, the combination of the references does not explicitly teach capsaicin treats of neuropathic pain as claimed by claim 17.

US '180 teaches that capsaicin and its analog are extremely effective therapy for treating neuropathic pain (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising layer and polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '983, US '501, US '671, and US '206, and use the patch to treat neuropathic pain as disclosed by US '180, because US '180 disclosed that capsaicin and its analog are extremely effective therapy for treating neuropathic pain, with reasonable expectation of having transdermal device comprising polysiloxane layer containing microreservoirs comprising a capsaicin in an amphiphilic solvent that treat neuropathic pain effectively.

Response to Arguments

10. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 7,063,860 teaches that capsaicin is a lipophilic drug used to treat neuropathic pain, and can be administered transdermally (col.5, lines 15-20, 34-43; col.22, line 25).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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